

Rejection Under 35 U.S.C. § 101

Claims 1-6 stand rejected under 35 U.S.C. § 101 for not being supported by either a specific or substantial asserted utility or a well-established utility. The Examiner asserts that the claimed compound of formula I in claim 1 provided the use as a "starting material or an intermediate for synthesizing a pharmaceutical product or agricultural chemical . . ." is not a substantial utility that defines a "real world" use. The Examiner states that even though the present invention provides the example of 5-methylproline methyl ester, as one of the products of the claimed compound in a reaction, the applicant fails to provide direction so that one of ordinary skill in the art would know how to use the claimed compound. The Examiner further cites the MPEP § 2107.07 to define "substantial utility" and argues that without specific examples of agricultural chemicals or a direction towards the general use of these agricultural chemicals, it would require someone of ordinary skill in the art further research to identify the use of the claimed compound.

In response, Applicants respectfully assert that the general rule, according to the MPEP 2107 regarding chemical compounds as

starting materials or intermediates is that to possess utility, the compounds must be used for more than simply generating other chemical compounds that are also of unknown utility. However, if the compounds are used to produce other chemical compounds of known usefulness, then the utility is shown.

Applicants respectfully submit that the chemical compounds of the present invention can be used as a starting material or an intermediate for synthesis of a known pharmaceutical product.

Applicants would like to submit a patent publication of EP 0618926 B1 (corresponding to WO 93/11152) to further support that the present invent has substantial and specific utility. In the EP 0618926 B1, paragraph [0001], it specifically states that the compound of Formula I of the EP reference is used as a competitive inhibitor of thrombin. 5-methylproline is an important partial structure of the compound represented by Formula I of EP 0618926 B1. Accordingly, the 5-methylproline methyl ester obtained in Reference Example I of the present invention (page 41-42) can be easily converted into the carboxylic acid form by alkali hydrolysis or acid hydrolysis. The carboxylic acid form of 5-methylproline can be used to produce H-(R)Cha-Pro(5-(S)Me)-NagX₂HCl and HOOC-CH₂-(R)Cha-Pro(5-(S)Me)-NagXHOAc (EP0618926, page 43, examples 79 and 80), both of which are competitive inhibitors of thrombin that are used as anticoagulants for prophylaxis and treatment of thromboembolic

diseases such as venous thrombosis, pulmonary embolism, arterial thrombosis (EP0618926, page 2, paragraph [0001]).

It should be noted that the compound represented by Formula I of EP0618926 (page 3) is a peptide derivative, and it is clearly understood that the compound can be derived from amino acids that constitute the compound. Specific compounds of Formula I are exemplified as $\text{HOOC-CH}_2\text{-(R)Cha-Pro(5-(R,S)Me)-Nag}$ and $\text{HOOC-CH}_2\text{-(R)Cha-Pro(5-(S)Me)-Nag}$ in claims 9 and 10 of EP0618926.

It would be clearly understood for those skilled in the art that 5-methylproline, being a constructive element of these compounds, can be easily prepared by carrying out hydrolysis of 5-methylproline methyl ester obtained from the compound of the present invention.

Therefore, Applicants respectfully submit that, in view of EP0618926, one skilled in the art would realize the substantial and specific utility of the present invention.

The ground for the 35 U.S.C. § 101 rejection is obviated and thus, withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. § 112

Claims 1-6 are also rejected under 35 U.S.C. § 112, first paragraph, for the same reasons as set forth in the 35 U.S.C. § 101 rejection.

As discussed in Applicants' response to the 35 U.S.C. § 101 rejection, one skilled in the art would clearly know how to use the claimed invention in view of EP0618926.

The grounds for this rejection have been obviated and thus, withdrawal of the 35 U.S.C. §112, first paragraph, rejection is respectfully requested.

Lastly, the Office Action cites EP 1000937 as the closest prior art. In response, Applicants respectfully assert that although 5-alkoxy-2(3H)oxazolone compound is actually used in the claimed process of claim 5 of the present invention, the final product of this process is 7a-alkoxy-4H-pyrano[3,2-d]-oxazol-2(3H)-one, not 5-alkoxy-2(3H)oxazolone. Similarly, the compounds claimed in claims 1 to 4 are 7a-alkoxy-4H-pyrano[3,2-d]-oxazol-2(3H)-one, not 5-alkoxy-2(3H)oxazolone. Thus, the present invention is distinguishable from EP 1000937.

Accordingly, in view of the above remarks, reconsideration of the rejections and allowance of the claims of the present application are respectfully requested.

C O N C L U S I O N

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed

that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

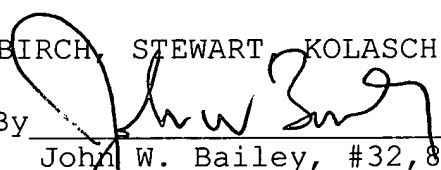
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Ping Wang, M.D. (Reg. No. 48,328) at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.


Respectfully submitted,

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